REMARKS

I. INTRODUCTION

New claims 21 - 25 have been added. Claims 1 - 25 are now pending in the present application. No new matter has been added. In view of the following remarks, it is respectfully submitted that all of the presently pending claims are allowable.

II. THE 35 U.S.C. § 102(b) REJECTION OVER U.S. PAT. NO. 6,569,106 SHOULD BE WITHDRAWN

Claims 1-9, 12, 13, and 15-17 stand rejected under 35 U.S.C. § 102(b) as unpatentable over U.S. Pat. No. 6,569,106 (Ullman). (See 3/22/2006 Office Action, p. 3, ¶ 1).

Claim 1 recites a protective package for an elongated medical device comprising "a protective sheath including a lumen sized to receive a body of the elongated medical device, wherein *a first end of the sheath is adapted to receive a distal end of the elongated medical device and a second end of the sheath is adapted to receive a proximal end of elongated medical device*" and "a hydration opening disposed between the first and second ends of the sheath."

The Examiner has substantially restated the previous final rejection stating that Fig. 4 of Ullman shows a protective package for an elongated medical device including a protective sheath (i.e., the fixed spiraling guide 27) and a hydration opening, as recited in claim 1. Applicants respectfully submit that neither the isolation chamber 13 nor the fixed spiraling guide 27 of Ullman is a protective *sheath* "wherein a first end of the sheath is adapted to receive a distal end of the elongated medical device and a second end of the sheath is adapted to receive a proximal end of the elongated medical device," as recited in claim 1. In addition, the Examiner relies on the statement in col. 3, lines 29 - 30 that the container of Ullman may be employed, "with some modification apparent to those skilled in the art, to house catheteters." Ullman provides no mention of what these modifications may be. In any case, Ullman seems to suggest that the container would be similar to the isolation chamber 13. Perhaps this statement alludes to changes in the dimensions of the structures which will receive the catheter (e.g., the opening into which the end of the catheter will be inserted). However, this is pure speculation and there is no basis for any suggestion that such a modified chamber would bear any more resemblance to a sheath than the isolation chamber 13.

In addition, although the Examiner stated that Ullman "discloses a structure which meets the definition of sheath, particularly with respect to the function of a sheath of a blade," the Examiner has never applied this definition to the components of the device of Ullman. Specifically, as stated previously it is respectfully submitted that the term sheath does not encompass any structure into which an item may be inserted. That is, a parking garage is not a sheath for a car. Rather a sheath is a "case for a blade...or other instrument *to which it fits closely*." (Webster's Third International Dictionary, 1986). If there is one thing a sheath does not do, it does not allow the end of the item inserted thereinto to float about freely. The reason a sheath fits a blade snugly is self-evident making clear the characteristic all sheaths have in common: that the item to be received therein is received snugly.

The Examiner states that the fixed spiraling guide 27 is a sheath as claimed. Ullman states only that the guide 27 "establishes a fixed pathway to ensure the guide wire 16 will spiral in a selected manner without entanglement." *Ullman*, col. 5, lines 14-16. Fig. 4 shows this guide 27 as a coiled wall which will engage only a leading tip and a radially outer side of a wire 16 inserted into the device 10. That this guide 27 is not a sheath is made clear from Fig. 4 which shows that a width of a proximal portion of the passage through which the wire 16 will be inserted is significantly smaller than a width of the passage defined by the guide 27 -- several times smaller. Thus, it is respectfully submitted that it is improper to infer that the space within the guide 27 closely fits the wire 16. In addition to the increased width of this space within the guide 27, it is noted that Ullman provides absolutely no disclosure of the size or shape of this space in a direction perpendicular to the plane of Fig. 4 (i.e., a width of the chamber 13). Furthermore, the guide 27 ends at an open central chamber which leaves the distal portion of the wire 16 completely uncontained. Thus, applicants respectfully submit that the spiraling guide 27 is not a sheath as recited in claim 1.

Furthermore, the Examiner maintains that the isolation chamber 13 is suitable to receive an entire guide wire 16 encompassing both its distal and proximal ends. However, it is noted that this suggestion is contrary to the disclosure of Ullman. In fact, Ullman states that "the wire is pushed all the way in [the chamber] until a small amount, such as about 1-2 cm, remains external to the membrane." *Ullman*, col. 2, lines 60-62. A lagging tip 16a is never received by the chamber 13 so that the wire may be easily removed from the chamber 13. The Examiner previously stated that "the funnel portion [18-20] is suitable to receive the end of the guide wire or catheter entirely within the funnel portion, and yet still allow easy removal of the guide wire or catheter from the package." *7/19/05 Office Action*, p. 6. The Examiner has not explained how

the guide wire would be removed from the isolation chamber 13 if the tip 16a were not external to the chamber 13 and it remains unclear how a user would pull the guide wire 16 from the chamber 13 when the tip 16a is located within the chamber 13. As stated previously, if the Examiner is implying that, while within the funnel portion, the lagging tip of the guide wire 16 could still be grasped for removal therefrom, this indicates clearly that this funnel portion also does not constitute a sheath. That is, it clearly does not fit the item inserted therein closely. As in the case of a sheath for a blade, such increased width allowing access is the very thing a sheath is designed to prevent. Thus, it is respectfully submitted that neither the chamber 13, the funnel portion thereof or the guide 27 (or any combination of these elements) constitutes a sheath as recited in claim 1.

Thus, applicants respectfully submit that claim 1 is allowable over Ullman and withdrawal of this rejection is respectfully requested. Because claims 2 - 9, 12 - 13 and 15 - 17 depend directly or indirectly from claim 1, it is submitted that these claims are allowable for the same reasons.

Furthermore, claim 3, which depends directly from claim 1, recites "a protective assembly disposed at the first end of the sheath, the protective assembly being adapted to maintain a desired shape of the distal end." Applicants respectfully submit that neither the funnel 18 nor any other structure of the device 10 in Ullman may be considered "a protective assembly" as recited in claim 3.

Ullman specifically states that the funnel 18 "acts as a transition structure to enable a healthcare provider to easily insert the guide wire 16 into an entry port, such as the entry ports 21-23, of the isolation chambers 13-15." *Ullman*, col. 4, lines 52-55. The funnel 18 simply guides the guide wire 16 into the isolation chamber 13. Also, as stated above, the tip 16a remains exposed from the funnel 18. While this allows the provider to grasp the tip 16 to pull the guide wire 16 from the isolation chamber 13, the funnel 18 is no way protects the tip 16a, or any portion, of the guide wire 16.

Furthermore, a shape of the funnel 18, which is shown in Fig. 4 of Ullman, does maintain a desired shape of the distal end of the elongate medical device. Initially, Ullman never discloses that the distal end, or any end of the guide wire 16, has a preformed shape which is integral to its function or requires maintenance. In any case, the structure of the funnel 18 is completely unsuitable for maintaining the shape of an end of the guide wire 16. The leading end may

contact the funnel 18 and be directed into the isolation chamber 13 when the guide wire 16 is inserted therein, and the lagging tip (tip 16a) is exposed with the funnel 18 surrounding it, as shown in Fig. 2. The funnel 18 never encloses or encases an end of the guide wire 18 protecting the shape thereof.

Thus, it is respectfully submitted that Ullman neither discloses nor suggests a " protective assembly being adapted to maintain a desired shape of the distal end," as recited in claim 3 and that claim 3 is also allowable for these further reasons.

Claim 6, which depends from claim 3, recites that "the protective assembly is adapted to prevent damage to a curvature of the distal end of the elongated medical device."

Applicants respectfully submit that the funnel 18 does not prevent damage to a curvature of the distal end, or any portion, of the elongated medical device. As noted above, the funnel 18 is meant to facilitate insertion of the guide wire 16 into the isolation chamber 13 by directing the leading tip of the guide wire 16 toward a chamber port 21 at a center of the funnel 18. *Ullman,* col. 4, lines 49 - 55, Fig. 2. However, the funnel 18 does not prevent damage to a curvature of the guide wire 16, if it even possesses a curvature to begin with. For example, as understood by those of skill in the art, if the guide wire 16 is advanced toward the funnel 18 and engages the funnel 18 at angle (e.g., substantially perpendicular to a surface of the funnel 18) and/or with enough force, the funnel 18 may cause the guide wire 16 to bend, damaging the curvature thereof. Additionally, the curvature of the lagging end of the guide wire 16 is not protected by the funnel 18. That is, the tip 16a is exposed in the opening of the funnel 18. While the tip 16a is exposed out of the opening of the funnel 18, the other end of the guide wire is unconstrained within the open portion of the isolation chamber 13. Thus, any curvature of either end of the guidewire unprotected by the isolation chamber 13.

It is respectfully submitted that Ullman neither discloses nor suggests that "the protective assembly is adapted to prevent damage to a curvature of the distal end of the elongated medical device," as recited in claim 6 and that claim 6 is allowable for this further reason as well.

Claim 8, which depends from claim 6, further recites a sheath "adapted to contain a catheter with a shaped distal tip."

Applicants respectfully submit that Ullman does not disclose a sheath adapted to contain

a catheter with a shaped distal tip. Initially, Ullman never discloses or suggests that the isolation chamber 13 is suitable to receive a guide wire 16 or any other structure having a shaped distal tip. Also, the funnel 18 of Ullman is not adapted to contain a catheter with a shaped distal tip. That is, the funnel 18 does not, in fact, even contain the guide wire 16, because the tip 16a is exposed in the opening thereof. Furthermore, Ullman does not disclose that either the funnel 18 or the opening thereof is shaped to complement the guide wire 16. Appellants also respectfully submit that it remains unclear how one of ordinary skill in the art would apply the teaching of Talonn to the funnel 18 of Ullman. That is, Talonn does not include any funnel-shaped portion. In fact, the cap 18, which is sized to complement the housing portion 17, completely covers the catheter, which is contrary to the teaching of the tip 16a remaining exposed in Ullman. Ullman specifically states that the tip 16a remaining exposed serves a predefined purpose, i.e., allows the provider to grasp the guide wire 16 and pull it from the isolation chamber 13.

Thus, Ullman neither discloses nor suggests that "the sheath is adapted to contain a catheter with a shaped distal tip," as recited in claim 8 and it is respectfully submitted that this claim is also allowable for this further reason.

Claim 15 recites a catheter kit comprising "a catheter having a shaped distal tip" in combination with a tubular enclosure having a length and an inner diameter corresponding, respectively, to a length and outer diameter of the catheter" and "a first end of the tubular enclosure being adapted to receive the shaped distal tip" and "a second end of the tubular enclosure being adapted to receive a proximal end of the catheter" in combination with "a hydration opening extending into an interior of the tubular enclosure between the first and second ends thereof, the hydration opening being positioned so that a desired proportion of flow thereinto is directed toward the first and second ends."

Additionally, Ullman does not disclose or suggest "a first end of the tubular enclosure being adapted to receive the shaped distal tip" and "a second end of the tubular enclosure being adapted to received a proximal end of the catheter," as recited in claim 15. The tip 16a of the guide wire 16 remains external to the chamber 13, and, as such, is never received therein.

Further, Ullman does not disclose or suggest a "hydration opening being positioned so that a desired proportion of flow thereinto is directed toward the first and second ends," as recited in claim 15. In support of the rejection of claim 15, the Examiner reads features of Ullman from the drawings, such as "both ends are below the port 30" and "even if the first end 26 were higher

than the port 30, which it is not." Initially, it respectfully submitted that Ullman does not disclose or suggest these features recited by the Examiner. Further, patent drawings are not to scale and any inferences made by the Examiner regarding dimensions and/or structural features of the device without supporting disclosure are improper. Appellants also respectfully submit that fluid delivered to the isolation chamber 13 via the filling port 30 is never directed toward the entry port 21. Ullman states that the fluid fills the isolation chamber 13, but never discloses or suggests that any fluid would be directed toward the entry port 21. Thus, it is respectfully submitted that Ullman neither discloses nor suggests the limitations of claim 15.

Thus, applicants respectfully request that the rejection under 35 U.S.C. § 102(b) of claim 15 - 17 be withdrawn.

III. THE 35 U.S.C. § 102(b) REJECTION OVER U.S. PAT. NO. 6,569,106 SHOULD BE WITHDRAWN

Claims 1 - 7 and 9 - 14 stand rejected under 35 U.S.C. § 102(b) as unpatentable over U.S. Pat. No. 6,588,588 (Samuels). (See 3/22/2006 Office Action, p. 8, ¶ 2).

Applicants respectfully submit that Samuels neither discloses nor suggests "a hydration opening disposed between the first and second ends of the sheath." Samuels describes a hoop packaging tube 40 consisting of a leading opening 44 and a trailing opening 48. *Samuels*, Fig. 1. An adapter 10 connecting the openings 44 and 48 includes a funnel 24 for receiving one or more guidewires 60. The guidewire 60 is inserted into the tube 40 via the adapter 10, winding wind around the tube 40 until the guidewire 60 has been fully inserted therein. *Id.* at Fig. 3. At no point does Samuels teach or suggest that the adapter 10 is suitable for receiving fluid or that fluid inserted thereinto would hydrate the tube 40. In fact, Samuels states that "[a]fter the guidewire is reinserted into the packaging tube, the adapter 10 may be removed...and the bridge connector may be reinserted to close the loop of the packaging tube." *Samuels*, col. 3, lines 40-44.

The Examiner states that a port 30 on the adapter 10 is usable as a hydration opening, and that further evidence of this use is provided in U.S. Patent No. 6,375,006 to Samuels ("'006 patent"). The '006 patent describes a flexible pipe 12 having a sealed end 14 and an open end 16 with a nozzle 20 attached thereto. It is never disclosed or suggest that the nozzle 20 is "disposed between the first and second ends" of the pipe 12. In fact, this would be contrary to the disclosure of the '006 patent which repeatedly describes the apparatus as having one open end

and one sealed end, which teaches away from the present invention. Further, the combination of these references would be improper, because Samuels teaches two open ends, whereas the '006 patent teaches only one open end. Thus, it is respectfully submitted that neither Samuels nor the '006 patent discloses or suggests "a hydration opening disposed between the first and second ends of the sheath," as recited in claim 1.

Thus, applicants respectfully request withdrawal of the rejection under 35 U.S.C. § 102(b) of claim 1 and claims 2, 4, 5, 7 and 9 - 14 which depend therefrom.

In regard to claim 3, it is noted that neither the adapter 10 nor any other structure of the device in Samuels may be considered "a protective assembly" as recited in claim 3. As noted above, the adaptor 10 simply facilitates reinsertion of a guidewire into a previously opened packaging tube 40. Specifically, Samuels states that:

> [t]he joining configuration of the adapter ends and the packaging tube ends prevents a medical guidewire from getting stuck on the junctions between the packaging tube 40 and the adapter 10 during insertion.

Samuels, col. 3, lines 37 - 40. At no point does Samuels disclose or suggest that the adapter 10 protects any portion of the guidewire, and, in particular, a shaped distal end thereof. Essentially, the adapter 10 is a conduit which simply expands the ends 46 and 48 of the packaging tub 40 allowing the guidewire to be inserted thereinto. *Samuels*, col. 3, lines 5 - 12. It is unclear how an inside of the adapter 10 is a protective assembly which is adapted to maintain a desired shape of the distal end of the guidewire, as the Examiner has suggested. Samuels does, however, suggest that the adapter 10 may be enlarged to accommodate several guidewires. *Samuels*, col. 3, lines 50 - 55. However, enlarging the adapter only relates to increased-diameter guidewires and would not maintain the shapes thereof. Thus, it is respectfully submitted that Samuels neither discloses nor suggests "a protective assembly disposed at the first end of the sheath, the protective assembly being adapted to maintain a desired shape of the distal end," as recited in claim 3.

Thus, applicants respectfully request withdrawal of the rejection under 35 U.S.C. § 102(b) of claim 3.

In regard to claim 6, it is noted that Samuels does not disclose or suggest a protective assembly "adapted to prevent damage to a curvature of the distal end of the elongated medical device," as recited in claim 6.

In view of the above-description of the adapter 10 and the description in Samuels, it remains unclear how the adapter 10 prevents damage to a curvature of any portion of the guidewire, and, in particular, the distal end. In fact, the adapter 10 induces a curvature on the guidewire when it is being inserted into the packaging tube 40. Samuels states that a longitudinal axis of a duct 26 "forms an angle of less than 90 degrees with the longitudinal axis 15 of the conduit passage 14...." Samuels, col. 3, lines 29 - 34. The angle of the duct 26 relative to the tube 40 will induce a curvature on the guidewire as it is inserted into the tube regardless of a preformed curvature of the guidewire. By inducing a curvature on the guidewire, the preformed curvature of the guidewire may be damaged, if they are opposed. Thus, it is respectfully submitted that Samuels neither discloses nor suggests a protective assembly "adapted to prevent damage to a curvature of the distal end of the elongated medical device," as recited in claim 6.

Thus, applicants respectfully request withdrawal of the rejection under 35 U.S.C. § 102(b) of claim 6.

IV. THE 35 U.S.C. § 103(a) REJECTION OVER U.S. PAT. NO. 6,588,588 IN VIEW OF U.S. PAT. NO. 6,569,106 SHOULD BE WITHDRAWN

The Examiner has rejected claims 8 and 15-20 under 35 U.S.C. § 103(a) as unpatentable over U.S. Pat. No. 6,588,588 (Samuels) in view of U.S. Pat. No. 6,569,106 (Ullman). (See 3/22/2006 Office Action, p. 10, ¶ 3). Samuels and Ullman have been discussed above.

Claim 8 depends from and therefore includes all the elements and limitations of independent claim 1. Claim 8 has been recited above and discussed with reference to Samuels. Claim 8 depends from claim 6 which depends from claim 3 which have been recited above and discussed with reference to Ullman. Thus, it is respectfully submitted that neither Samuels nor Ullman, either alone or in combination, discloses a sheath "adapted to contain a catheter with a shaped distal tip," as recited in claim 8. Accordingly, Applicants respectfully request that the Examiner withdraw the 35 U.S.C. § 103(a) rejection of claim 8.

Claim 15 has been recited above and discussed with reference to Ullman. The Examiner has correctly stated that Samuels does not disclose the package being used with a catheter. The Examiner attempts to cure this deficiency with Ullman. However, regarding the following remarks, it is respectfully submitted that the deficiency and cure for claim 15 is moot since

Samuels does not cure the above-described deficiencies of Ullman. Specifically, neither Samuels nor Ullman, either alone or in combination, discloses or suggests "the hydration opening being positioned so that a desire proportion of flow thereinto is directed toward the first and second ends," as recited in claim 15.

As described above, Samuels does not disclose or suggest that the adapter 10 or the tube 40 are suitable for hydration. The Examiner maintains that a port 30 on the adapter 10 is usable as a hydration opening, and that further evidence of this use is provided in the '006 patent (U.S. Patent No. 6,375,006 to Samuels). As noted above, the '006 never discloses or suggests that the nozzle 20 is "disposed between the first and second ends" of the pipe 12. In fact, this would be contrary to the disclosure of the '006 patent which repeatedly describes the apparatus as having one open end and one sealed end, teaching away from the present invention. Furthermore, Ullman does not teach that saline solution inserted into the chamber 13 via the filling port 30 is directed in any manner toward the two ends of the chamber 13. That is, as described above, fluid delivered to the isolation chamber 13 via the filling port 30 is never directed toward the entry port 21. Ullman does state that the fluid fills the isolation chamber 13 from the bottom-up, but never discloses or suggests that any fluid would be directed toward the entry port 21. Thus, it is respectfully submitted that neither Samuels nor Ullman, either alone or in combination, discloses or suggests "the hydration opening being positioned so that a desire proportion of flow thereinto is directed toward the first and second ends," as recited in claim 15.

Accordingly, Applicants respectfully request that the Examiner withdraw the 35 U.S.C. § 103(a) rejection of claim 15. Because claims 16 - 20 depend from and, therefore, include the limitations of claim 15, it is respectfully submitted that these claims are allowable for at least the reasons stated above.

V. THE 35 U.S.C. § 102(b) REJECTION OVER U.S. PAT. NO. 3,861,395 SHOULD BE WITHDRAWN

The Examiner has rejected claims 1, 3, 6-9, 12, 13, 15, 16, and 19 under 35 U.S.C. § 102(b) as unpatentable over U.S. Pat. No. 3,861,395 (Taniguchi). (See 3/22/2006 Office Action, p. 11, ¶ 4).

The Examiner previously stated that Taniguchi shows a reservoir 31 disposed between a

proximal end of the body 12 and a distal end of the bag 70. It should be noted that Taniguchi does not provide any disclosure with regard to reference numeral 31 and does not include any mention of "a reservoir." Thus, it is unclear what feature numeral 31 is drawn to and what function is performed by this element. Taniguchi does provide, however, that a lubricant bladder 32 is punctured by a spike 33 when a cover 30 enclosing the bladder 32 is depressed. The bladder 32 empties onto a proximal end of a catheter 68. It is respectfully submitted that a one-time covering of the proximal end of the catheter 68 in lubricant cannot be equated to the "hydration opening," as recited in claim 1. Thus, it is respectfully submitted that Taniguchi does not disclose or suggest "a hydration opening disposed between the first and second ends of the sheath," as recited in claim 1.

The Examiner suggests that the body 12 combined with the bag 70 makes up a structure equateable with the recited "protective sheath." Applicants respectfully submit that the body 12 and the bag 70 are separate structures, neither of which can be considered a protective sheath, as recited in claim 1.

Thus, applicants respectfully request withdrawal of the rejection under 35 U.S.C. § 102 of claim 1 and claims 1, 3, 6-9, 12, 13 which depend therefrom.

It is resepectfully submitted that claim 15 and claims 16, and 19 which depend therefrom are allowable for the same reasons stated above in regard to claim 1.

VI. THE 35 U.S.C. § 103(a) REJECTION OVER U.S. PAT. NO. 3,861,395 IN VIEW OF U.S. PAT. NO. 4,805,611 SHOULD BE WITHDRAWN

The Examiner has rejected claim 4 under 35 U.S.C. § 103(a) as unpatentable over U.S. Pat. No. 3,861,395 (Taniguchi) in view of U.S. Pat. No. 4,805,611 (Hodgkins). (See 3/22/2006 Office Action, p. 13, ¶ 5).

The Examiner has correctly stated that Taniguchi does not disclose a luer or adapter capable of receiving a syringe. The Examiner has attempted to cure this deficiency with Hodgkins. However, in view of the above remarks concerning the failure of Taniguchi to teach or suggest elements of claim 1 from which claim 4 depends, it is submitted that, as Hodgkins fails to cure these defects, claim 4 is allowable for the same reasons as claim 1.

Specifically, Hodgkins discloses an aspirating device consisting of a flexible catheter which is adapted for insertion into the trachea. (See Hodgkins, Abstract). A flexible envelope is connected to the device so that substantially all portions of the catheter between a catheter connector fitting and a proximal opening of the device are within the envelope. (See Id.) As such, it is respectfully submitted that Hodgkins does not cure the above-described deficiencies of Taniguchi. Thus, because claim 4 depends from, and, therefore includes all of the elements recited in claim 1, it is respectfully submitted that neither Hodgkins nor Taniguchi, either alone or in combination, discloses or suggests the subject matter of claim 4.

Accordingly, it is respectfully requested that the Examiner withdraw the 35 U.S.C. § 103(a) rejection of claim 4.

V. THE 35 U.S.C. § 102(b) REJECTION OVER U.S. PAT. NO. 6,258,072 SHOULD BE WITHDRAWN

Claims 1, 3-9, and 11-13 stand rejected under 35 U.S.C. § 102(b) as unpatentable over U.S. Pat. No. 6,258,072 (Weinberger). (See 3/22/2006 Office Action, p. 14, ¶ 6).

Weinberger describes a catheter protective device for "protecting the proximal sections of catheters and minimizing blood loss during catheter exchanges." (Col. 1, lines 5 - 8). "Typically at the proximal end of the guide catheter there will be a "Y" adaptor [sic] having two or more manifolds or ports for the introduction of and removal of guidewires, catheters and the like." (Col. 1, lines 25 - 28). These "Y" adapters remain outside the body while the distal end of the catheter is inserted into the body. Thus, they are expressly designed to cover only a short length of the proximal portion of the catheter and are not designed to hold or protect either the proximal end or the distal end of the catheter. The proximal end of the catheter or guide wire inserted through the "Y" adapter 10 projects proximally beyond the proximal end of the adapter 10 while the distal end of the device 26 extends distally beyond the distal end of the adapter 10 into the body. In this case it is clear that no fluid injected into the adapter 10 can pass to either end of a catheter received therein.

Thus it is respectfully submitted that Weinberg fails to show or suggest a protective package for an elongated medical device, comprising "a protective sheath including a lumen sized to receive a body of the elongated medical device, wherein *a first end of the sheath is adapted to receive a distal end of the elongated medical device* and *a second end of the sheath is*

adapted to receive a proximal end of the elongated medical device," and "a hydration opening disposed between the first and second ends of the sheath."

Accordingly, Applicants respectfully request that the Examiner withdraw the 35 U.S.C. § 102(b) rejection of claim 1. Because claims 3-9 and 11-13 depend from and, therefore, include the limitations of claim 1, it is respectfully submitted that these claims are allowable for at least the reasons stated above.

VI. THE 35 U.S.C. § 102(b) REJECTION OVER U.S. PAT. NO. 5,427,114 SHOULD BE WITHDRAWN

The Examiner has rejected claims 1, 3-9, 11-13, 15, 16, 19, and 20 under 35 U.S.C. § 102(b) as unpatentable over U.S. Pat. No. 5,427,114 (Colliver). (See 3/22/2006 Office Action, p. 15, ¶ 7).

As recited above, claim 1 recites a "protective package for an elongated medical device" comprising "a protective sheath including a lumen sized to receive a body of the elongated medical device, wherein a first end of the sheath is adapted to receive a distal end of the elongated medical device and a second end of the sheath is adapted to receive a proximal end of the elongated medical device" and "a hydration opening disposed between the first and second ends of the sheath."

In contrast, Colliver simply shows a catheter with multiple internal conduits fixed therein. It is respectfully submitted that Colliver neither shows nor suggests any "protective package for an elongated medical device" and clearly neither shows nor suggests "a protective sheath including a lumen sized to receive a body of the elongated medical device" as recited in claim 1. Specifically, as stated above, it is respectfully submitted that the term sheath does not encompass any structure into which an item may be inserted. That is, a parking garage is not a sheath for a car. Rather a sheath is a "case for a blade...or other instrument *to which it fits closely*." (Webster's Third International Dictionary, 1986). The catheters 30, 32 are not snugly received within the catheter 10 as seen clearly in each of Figs. 2 - 5. Thus, it is respectfully submitted that the catheter 10 of Colliver does not constitute a "protective package for an elongated medical device" including "a protective sheath including a lumen sized to receive a body of the elongated medical device" as recited in claim 1.

In addition, it is noted that the inner catheters 30, 32 of Colliver pass through a catheter plug 64 located immediately proximal to the infusion port 14. (*See*, Fig. 5 and col. 5, lines 53 - 57). This catheter plug 64 forms a "hermetic seal so that vacuum calibration may occur via vacuum calibration port 18." (*Id.*, col. 5, lines 58 - 60). Thus, no fluid can flow past the plug 64 toward the proximal ends of the catheters 30, 32. Furthermore, the distal ends of the catheters 30, 32 are also prevented from contacting fluids inserted via the port 14 as they are sealed within the pressure sensors (e.g., pressure sensor 45). That is, for the sensor 45 to operate properly, the fluid pressure on the proximal side of the diaphragm 51 must remain constant so that fluctuations in the fluid pressure on the distal side thereof will produce known changes in the shape of the diaphragm 51. (*See*, col. 6, lines 1 - 16). Thus, it is respectfully submitted that Colliver also neither shows nor suggests "a hydration opening" as recited in claim 1.

Accordingly, Applicants respectfully request that the Examiner withdraw the 35 U.S.C. § 102(b) rejection of claim 1. Because claims 3-9 and 11-13 depend from and, therefore, include the limitations of claim 1, it is respectfully submitted that these claims are allowable for at least the reasons stated above.

Independent claim 15 recites a catheter kit comprising "a catheter *having a shaped distal tip*" and "a tubular enclosure having a length and an inner diameter corresponding, respectively, to a length and outer diameter of the catheter" in combination with "a first end of the tubular enclosure being adapted to receive the shaped distal tip, a second end of the tubular enclosure being adapted to receive a proximal end of the catheter" and "a hydration opening extending into an interior of the tubular enclosure between the first and second ends thereof, the hydration opening being positioned so that a desired proportion of flow thereinto is directed toward the first and second ends."

It is noted that Colliver provides no disclosure of either "a catheter having a shaped distal head," or "a tubular enclosure having a length and an inner diameter corresponding, respectively, to a length and outer diameter of the catheter," as recited in claim 15. That is, there is no suggestion that the catheters 30, 32 may have a shaped distal tip. Applicants respectfully submit that the catheters in Colliver are depicted as linear. (*See*, Figs. 2 - 3). Thus, Applicants respectfully submit that this claim is allowable for the same reasons stated above with reference to claim 1 as well as this additional reason.

Accordingly, Applicants respectfully request that the Examiner withdraw the 35 U.S.C. §

102(b) rejection of claim 15. Because claims 16, 19, and 20 depend from and, therefore, include the limitations of claim 15, it is respectfully submitted that these claims are allowable for at least the reasons stated above.

In addition, claim 20 recites a hydration opening "substantially equidistant between the first and second ends." Colliver shows the infusion port 14 distant from the distal pressure sensor 45 in which the distal end of the catheter 30 is located and almost immediately proximal to the catheter adapter 40 at which the proximal ends of the catheters 30, 32. There is no specific reference to the positioning of the infusion port 14 with respect to ends of the inner catheters 30, 32 and this indication in the drawings teaches away from the recited "equidistant" positioning. Thus, it is respectfully submitted that Colliver neither discloses nor suggests a hydration opening "substantially equidistant between the first and second ends," as recited in claim 20.

New claim 21 recites a "protective package for removably receiving an elongated medical device" comprising "a protective sheath including a lumen sized to tightly fit a body of the elongated medical device to be received therein, a first end of the sheath being adapted to receive a distal end of the elongated medical device and a second end of the sheath being adapted to receive a proximal end of the elongated medical device" in combination with "a hydration opening disposed between the first and second ends of the sheath so that fluid supplied to the sheath via the hydration opening is provided to the first and second ends of the sheath."

It is respectfully submitted that this claim and new claims 22 - 25 which depend therefrom are allowable for the same reasons stated above in regard to claims 1 and 15.

CONCLUSION

In light of the foregoing, Applicants respectfully submit that all of the now pending claims are in condition for allowance. All issues raised by the Examiner having been addressed, and an early and favorable action on the merits is earnestly solicited.

Respectfully submitted,

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By: _____
Oleg F. Kaplun (Reg. No. 45,559)

Fay Kaplun & Marcin, LLP
150 Broadway, Suite 702
New York, NY 10038
Tel: (212) 619-6000
Fax: (212) 619-0276